IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

Supreme Court, U. S.
FILED
JUL 30 1979
MICHAEL RODAK, JR., CLE

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

MOTION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE, AND BRIEF AS AMICI CURIAE, OF

JOSEPH CIMINO, M.D., M.P.H., M.I.H.
HARRY B. DEMOPOULOS, M.D.
DAVID KRITCHEVSKY, Ph.D.
ELIZABETH C. MILLER, Ph.D.
JAMES MILLER, Ph.D.
PAUL M. NEWBERNE, Ph.D.
STEVE TANNENBAUM, Ph.D.
BERNARD M. WAGNER, M.D.
VERNON R. YOUNG, Ph.D.

AS INDIVIDUAL MEDICAL SCIENTISTS RELATING TO THE SCIENTIFIC (DERMAL CONTACT) ISSUE

JAMES R. RICHARDS
1101 17th Street, N.W.
Washington, D.C. 20036
Counsel

July 30, 1979

PRESS OF BYRON S. ADAMS PRINTING, INC., WASHINGTON, D. C.

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MOTION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE OF JOSEPH CIMINO, M.D., M.P.H., M.I.H., HARRY B. DEMOPOULOS, M.D., DAVID KRITCHEVSKY, Ph.D., ELIZABETH C. MILLER, Ph.D., JAMES MILLER, Ph.D., PAUL M. NEWBERNE, Ph.D., STEVE TANNENBAUM, Ph.D., BERNARD M. WAGNER, M.D., AND VERNON R. YOUNG, Ph.D., AS INDIVIDUAL MEDICAL SCIENTISTS

Drs. Joseph Cimino, Harry B. Demopoulos, David Kritchevsky, Elizabeth C. Miller, James Miller, Paul

M. Newberne, Steve Tannenbaum, Bernard M. Wagner, and Vernon R. Young (hereinafter the "individual scientists") hereby respectfully move, pursuant to Rule 42 of the Court, for leave to file the attached brief as *amici curiae* in the above-captioned consolidated cases.

The Solicitor General, on behalf of petitioner in No. 78-1036, has consented to the filing of the attached brief.[1] Similarly, counsel for all respondents in the consolidated cases have granted consent.[2] However, by a letter dated July 13, 1979, counsel for the Industrial Union Department, AFL-CIO ("IUD"), petitioner in No. 78-911, refused consent to the filing of a brief *amici curiae* by the individual scientists.[3]

In support of this motion, the individual scientists state the following:

1. The individual scientists are engaged in scientific research and other academic pursuits at teaching universities. Their qualifications are briefly summarized in note 1 of the attached brief.

2. The individual scientists have no pecuniary interest in this litigation. Among their various activities, they are engaged in conducting research and experimental programs which sometimes are, and more often should be, utilized by the United States Government in making health regulatory decisions. As academic scientists, they have a special perspective on the manner in

[1] The Solicitor General's consent is attached as Appendix A to this motion *infra*, at vi .

[2] Respondents' consents are attached as Appendices B-I to this motion *infra*, at vii-xiv.

[3] The IUD's refusal is attached as Appendix J to this motion *infra*, at xv-xvi.

which the scientific community can contribute to and strengthen the regulatory process by providing scientific data on questions as to which the Occupational Safety and Health Administration ("OSHA") and other agencies require prompt, reliable answers. If the government would determine to act on the basis of research and scientific data, this circumstance would motivate the scientific community to generate the required data. In particular, the individual scientists believe that presentation of their views may materially aid this Court's resolution of the second (dermal contact) issue in these cases, relating to the proper scientific basis required to support OSHA standards. None of the parties has the special perspective leading to analysis of the second issue from a scientific viewpoint. And it is counsel's understanding that none of the other corporations and organizations filing briefs *amicus curiae* are expected to address the second issue.

3. The individual scientists are filing this motion, and request leave to file the attached brief *amici curiae*, as individuals, and not as members of any organization, academic institution or other group. While the individual scientists believe their views have substantial support in the scientific community, the views expressed in the attached brief are solely those of the named individuals.

4. In refusing consent to the filing of a brief *amici curiae* by the individual scientists, counsel for the IUD noted that such consent had been requested on behalf of individual physicians and scientists, but stated that "it does not appear that your clients represent the entire 'scientific community' or even that they represent any particular scientific organization." App. I *infra*, at xvi. As stated above, the individual scientists seek

to present only their own views, and do not in any way purport to represent the views of any other person or group. A group of scientists (or other persons) with a common interest and perspective should be welcome to express their views to this Court in their individual capacities, without being required to locate or even create an organization through which they must state their position. To our knowledge, there is no requirement in this Court's rules or otherwise that only corporations or formal organizations can file briefs *amicus curiae* with the Court, and no such requirement should be imposed.

5. The IUD's other stated basis for refusing its consent was that the "IUD does not believe that the views of individual scientists as to what the record reflects are a proper subject for an *amicus* brief in the Supreme Court." *Id.* Whether or not the IUD is correct on this point is irrelevant to the present motion. The attached brief does not discuss the record evidence in these cases.

6. The attached brief *amici curiae* is addressed solely to the second (dermal contact) issue in these cases. As stated above, it is understood that none of the other organizations which have received the consent of all parties to file briefs *amicus curiae* in the cases will address the second issue. The IUD, the only party which refused consent to the filing of the attached brief, stated only the first issue in these cases in both its petition for certiorari and its brief on the merits, and the IUD's brief on the merits does not discuss the second (dermal contact) issue at all.

7. The attached brief is being filed within the time prescribed by Rule 42.

WHEREFORE, the individual scientists named above respectfully request that leave to file the attached Brief as Amici Curiae be granted.

Respectfully submitted,

JAMES R. RICHARDS
1101 17th Street, N.W.
Washington, D.C. 20036
Counsel

APPENDIX A

OFFICE OF THE SOLICITOR GENERAL
Washington, D.C. 20530

July 11, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: Industrial Union Department, AFL-CIO v. American Petroleum Institute, et al., No. 78-911; Ray Marshall, Secretary of Labor v. American Petroleum Institute, et al., No. 78-1036

Dear Mr. Richards:

On behalf of the federal parties, I consent to your filing a brief *amicus curiae* in these cases.

Sincerely yours,

/s/ WADE H. MCCREE, JR.
Wade H. McCree, Jr.
Solicitor General

APPENDIX B

CLEARY, GOTTLIEB, STEEN & HAMILTON
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036

July 11, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute, et al.*, No. 78-911; *Ray Marshall, Secretary of Labor* v. *American Petroleum Institute, et al.*, No. 78-1036.

Dear Mr. Richards:

Our clients, the Rubber Manufacturers Association, *et al.*, consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos and other individual physicians and scientists in the above-styled consolidated cases.

Very truly yours,

/s/ CHARLES F. LETTOW
Charles F. Lettow

cc: Counsel for all parties

APPENDIX C

KIRKLAND & ELLIS

1776 K Street, N.W.
Washington, D.C. 20006

July 12, 1979

James R. Richards, Esq.
Capital Legal Foundation
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: IUD v. API & Marshall v. API, Nos. 78-911 & 78-1036

Dear Mr. Richards:

On behalf of the American Petroleum Institute, *et al.*, we consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos in the above-styled case.

Sincerely,

/s/ EDWARD W. WARREN
Edward W. Warren

EWW: ma
cc: All Counsel

APPENDIX D

WILMER, CUTLER & PICKERING

1666 K Street, N.W.
Washington, D.C. 20006

July 11, 1979

James R. Richards, Esq.
Attorney at Law
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

On behalf of the American Iron and Steel Institute, we hereby consent to the filing, on behalf of Dr. Harry B. Demopoulos, *et al.*, of a brief *amicus curiae* in the above-captioned actions.

Very truly yours,

/s/ NEIL JAY KING
Neil Jay King

cc: All Counsel

APPENDIX E

E. I. DUPONT DE NEMOURS & COMPANY
INCORPORATED

Wilmington, Delaware 19898

July 12, 1979

Legal Department

James R. Richards, Esq.
Attorney at Law
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

Please be advised that on behalf of the Du Pont Company, we consent to your filing a brief *amicus curiae* in the above-captioned cases as counsel to Dr. Harry B. Demopoulos, et al.

Very truly yours,

/s/ JOHN F. DICKEY
John F. Dickey
Attorney
Environment Division

JFD: kes

APPENDIX F

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA

1101 Sixteenth St., N.W.
Washington, D.C. 20036

July 11, 1979

Mr. James R. Richards
Attorney At Law
1101 17th Street, N.W.
Suite 810
Washington, D.C.

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

The Independent Petroleum Association of America hereby consents to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos, et al., in the above-referenced case.

Sincerely,

/s/ HAROLD B. SCOGGINS, JR.
Harold B. Scoggins, Jr.

HBS: mk
cc: All Counsel

APPENDIX G

SELLERS, CONNER & CUNEO

Attorneys and Counselors
1625 K Street, Northwest
Washington, D.C. 20006

July 12, 1979

James R. Richards, Esq.
Attorney at Law
Suite 810
1101 Seventeenth Street, N.W.
Washington, D.C. 20036

Re: *IUD, AFL-CIO* v. *API, et al.*, No. 78-911
Marshall v. *API, et al.*, No. 78-1036

Dear Mr. Richards:

On behalf of our client, Chemical Specialties Manufacturers Association, we hereby consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos, et al., in the above-captioned actions.

Sincerely,

/s/ ROBERT L. ACKERLY
Robert L. Ackerly

rla/bcs
cc: Counsel for all parties

APPENDIX H

WILMER, CUTLER & PICKERING

1666 K Street, N.W.
Washington, D.C. 20006

July 16, 1979

James R. Richards, Esq.
Attorney at Law
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: *Industrial Union Department, AFL-CIO* v. *API*, No. 78-911; *Marshall* v. *API*, No. 78-1036

Dear Mr. Richards:

In reply to your letter of July 6, 1979, concerning the above-referenced cases, I advise you that respondent Manufacturing Chemists Association consents to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos and other individual physicians and scientists, including Dr. Joseph Cumino and Professor Benjamin Van Duren.

For your information, the Manufacturing Chemists Association has recently changed its name to the Chemical Manufacturers Association.

Sincerely yours,

/s/ JOHN H. PICKERING
John H. Pickering

cc: All Parties

APPENDIX I

PENNIE & EDMONDS

Counsellors at Law
330 Madison Avenue
New York, N.Y. 10017

July 11, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: IUD v. API & Marshall v. API, Nos. 78-911 and 78-1038

Dear Mr. Richards:

On behalf of the Republic Steel Corporation, we consent to the filing of a brief *amicus curiae* by Dr. Harry B. Demopoulos et al. in the above-styled case.

Very truly yours,

/s/ FRANK E. MORRIS
Frank E. Morris

cc: All Counsel

APPENDIX J

BREDHOFF, GOTTESMAN, COHEN & WEINBERG

Attorneys and Counselors
1000 Connecticut Avenue, N.W.
Washington, D.C. 20036

July 13, 1979

James R. Richards, Esq.
1101 17th Street, N.W.
Suite 810
Washington, D.C. 20036

Re: Industrial Union Department v. API, U.S. S.Ct. No. 78-911; Marshall v. API, U.S. S.Ct. No. 78-1036

Dear Mr. Richards:

This is to advise that the Industrial Union Department, AFL-CIO ("IUD") does not consent to your request to file a brief *amicus curiae* in the above-captioned case on behalf of "Dr. Harry B. Demopoulos and other individual physicians and scientists, including Dr. Joseph Cumino and Professor Benjamin Van Duren."

As you are undoubtedly aware, IUD has consented to the filing of *amicus* briefs in this case by several organizations, including the Capital Legal Foundation; and IUD would not ordinarily refuse such a request. However, having discussed with you the nature of your clients' claimed interest in this case, we have decided that your request should properly be refused.

Although your letter of July 6, 1979 requesting IUD's consent states that "the issues in these cases present questions of widespread interest in the scientific community," it does not appear that your clients represent the entire "scientific community," or even that they represent any particular scientific organization. Equally important, my understanding is that your clients merely have an academic interest in the manner in which certain scientific data in the record was interpreted by the Occupational Safety and Health Administration. While that might be a proper subject for testimony before the agency, IUD does not believe that the views of individual scientists as to what the record reflects are a proper subject for an *amicus* brief in the Supreme Court.

If I have in any way misunderstood the nature of your clients' interest in this case, do not hesitate to provide me with any additional information which you believe to be relevant to your clients' request.

Yours truly,

/s/ JEREMIAH A. COLLINS
Jeremiah A. Collins

cc: all counsel of record

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BRIEF AS AMICI CURIAE
OF

JOSEPH CIMINO, M.D., M.P.H., M.I.H.
HARRY B. DEMOPOULOS, M.D.
DAVID KRITCHEVSKY, Ph.D.
ELIZABETH C. MILLER, Ph.D.
JAMES MILLER, Ph.D.
PAUL M. NEWBERNE, Ph.D.
STEVE TANNENBAUM, Ph.D.
BERNARD M. WAGNER, M.D.
VERNON R. YOUNG, Ph.D.

AS INDIVIDUAL MEDICAL SCIENTISTS
RELATING TO THE SCIENTIFIC (DERMAL CONTACT) ISSUE

INTEREST OF THE AMICI

The individual academic scientists [1] who have joined in this brief as "scientist-citizens" believe that this case presents issues which are of critical and lasting

[1] The qualifications of the university scientists are briefly summarized below. Further details regarding titles of published papers, and sources of research funding are available and will be furnished to the Court upon request.

Joseph Cimino, M.D., M.P.H., Masters in Industrial Health, Harvard University. President of New York Medical College, Valhalla, New York; former Commissioner of Health of New York City, 1971-1974.

Harry B. Demopoulos, M.D. Associate Professor of Pathology, New York University Medical Center, New York, New York; former Director of Cancer Center Planning, New York University Medical Center, 1973-1975.

David Kritchevsky, Ph.D. Associate Director, Wistar Institute, University of Pennsylvania, Philadelphia, Pennsylvania.

Elizabeth C. Miller, Ph.D. Professor of Oncology and Associate Director of the McArdle Laboratory for Cancer Research, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin.

James Miller, Ph.D. Professor of Oncology and Associate Director of the McArdle Laboratory for Cancer Research, Comprehensive Cancer Center, University of Wisconsin, Madison, Wisconsin.

Paul M. Newberne, Ph.D. Professor of Nutritional Pathology, Massachusetts Institute of Technology, Cambridge, Massachusetts, member of the National Academy of Sciences Panel on Saccharin and Cyclamates.

Steve Tannenbaum, Ph.D. Professor of Food Chemistry, Massachusetts Institute of Technology, Cambridge, Massachusetts.

Bernard M. Wagner, M.D. Professor of Pathology, Columbia University College of Physicians and Surgeons, Comprehensive Cancer Center, New York, New York; Editor of *Human Pathology* and Associate Editor of the *Journal of Environmental Pathology and Toxicology*.

Vernon R. Young, Ph.D. Professor of Nutritional Biochemistry, Massachusetts Institute of Technology, Cambridge, Massachusetts.

interest to the role of science in relation to the regulatory process. This Court's decision will undoubtedly influence the degree to which the Occupational Safety and Health Administration ("OSHA") utilizes science in developing its standards.

The *scientific validity* of regulatory standards represents an important long-term challenge facing a technologically advanced economy such as ours. The potentially dangerous chemical/physical processes which our society has come to rely on more and more require regulations that are arrived at by the *best science available*, and not through guesswork, which by its nature is likely to be incorrect and costly in terms of lives, health and/or economic viability.

The purpose of the academic scientists in filing this brief is to offer the Court some insight into the ways in which studies by the scientific community in the United States and in other countries can contribute to and *strengthen* the regulatory process via short-term (2-4 month) research, on questions where OSHA and other regulatory agencies require rapid, assured answers. This nation has an extensive, and largely federally funded, academic research establishment which has not been sufficiently utilized to assist OSHA in its difficult regulatory decisions.

The *amici* have no pecuniary interest in the case, but wish to bring to the Court's attention the views of some of the academic scientists [2] on how scientific research may contribute to and strengthen the regulatory process. While the views expressed are shared by

[2] By using the term "academic scientists" we refer to ourselves as persons engaged in scientific research while also being active in the academic milieu of a teaching university.

many colleagues in the scientific community, this brief is filed by the scientists as individuals and not as representatives of an organization or institution.

SUMMARY OF ARGUMENT

Section 6(b)(5) of the Act requires that OSHA develop and promulgate standards on the basis of "research, demonstrations, [and] experiments". In that connection, there is a well-ordered, four-step process of scientific inquiry to deal with questions such as those regarding skin absorption of substances such as benzene. This four-step scientific inquiry involves analysis of existing information, identification of informational gaps, completion of specific experiments to close those gaps, and evaluation of experimental and other data to reach conclusions based on the exercise of scientific judgment. Much data, including skin absorption data, can be obtained within a two- to four-month period using rodents and other laboratory animals. The types of data which can be obtained within this relatively short period include skin absorption data, acute toxicity data, and skin irritation data.

Had OSHA approached the question of skin contact with benzene from the scientific point of view, using the four-step scientific inquiry outlined above, it would have identified the data needed to reach a sound scientific conclusion on workers' exposure to benzene from dermal contact with mixtures containing that substance. By an inquiry to the scientific community, OSHA would have learned that a number of biomedical research facilities would have been able to generate data on skin absorption of benzene in a two- to four-month period, using a simple and standard procedure. We do

not suggest that all data needed by OSHA can be generated in that short period; however, it happens that skin absorption data come within the two- to four-month category.

The substantial biomedical research establishment in the United States, developed in large measure as a result of extensive government experimental programs, has the capability to provide the scientific data required to implement the OSHA statute. The university biomedical research establishment has not been utilized to any great extent by OSHA because OSHA, unlike some other health regulatory agencies, has not made any systematic attempt to take advantage of the research and experimental capability of the academic biomedical research community. If this Court affirms the statutory objective that OSHA act on the basis of research and experimental data in establishing provisions of its standards, the biomedical research community can assist OSHA in obtaining vitally needed scientific information, in most cases in a reasonable time frame.

ARGUMENT

I. Scientific Approaches To Substantiating Regulatory Action

A. Introduction

When the Congress created OSHA in 1970, it recognized the need for *scientifically valid regulations.* Accordingly, Congress directed that OSHA's standards be based on "research, demonstration, experiments . . ." as well as "the latest available scientific data in the field . . . ." In contrast, some of OSHA's regulations, including the portion of OSHA's 1978 benzene standard banning dermal contact with benzene, were developed with insufficient scientific input.

The scientific component of the second issue in this case[3] is such that in reaching its decision, the Court may find it helpful to have a greater understanding of the approaches used in the rapidly advancing field of medical scientific research.

This brief first discusses the scientific community's understanding of "research, demonstrations, [and] experiments". It then discusses the way in which OSHA can make appropriate use of science in setting health standards, and the capability of the biomedical research establishment to supply scientific data to meet OSHA's needs.

B. Scientific description of "research, demonstrations, [and] experiments"

When questions are raised regarding the dangers of the possibly toxic dose levels of substances such as benzene, there is a well ordered, four-step process of scientific inquiry.

The *first step* is to gather the existing information by thoroughly searching the available literature. At present, this is a rapid and efficient procedure due to the extensive computer indexing of scientific papers. Scientists also collect unpublished data by attending

[3] This brief relates only to the dermal contact sections of OSHA's benzene standard (29 C.F.R. § 1910.1028(e)(2) and (h)) and in that context considers and discusses the second and third sentences of Section 6(b)(5) of the Occupational Safety and Health Act of 1970 (the "Act"), 29 U.S.C. § 655(b)(5). These provisions require that OSHA act on the basis of "research, demonstrations, [and] experiments" and other scientific information in promulgating standards under the Act. The *amici* recognize that the requirement that OSHA act on the basis of scientific information also relates to the first issue in this case, but in a different context, which is not addressed in this brief.

conferences and visiting the laboratories of their colleagues. From these sources, there are three types of available data: 1) data from experiments that have not as yet been duplicated; 2) data that have been verified by another group of independent scientists; and 3) data that appear to be contradicted by another group.

The *second step* is to identify the gaps between the information available, and the information needed to clarify those gaps. The scientist studies each area to determine which can be answered most rapidly and reliably, at reasonable cost, and also which areas might be a key that could narrow more than one gap.

The *third step* is to define the specific experiments needed to close the gaps. A major part of this is the identification of the multiple variables inherent in biomedical research which need to be controlled. For example, in considering dermal exposure to benzene, some of the variables requiring control include: the amounts; concentrations; duration; and anatomic site. The experiments considered would include use of laboratory animals, as well as perhaps case-controlled epidemiologic studies in the longer term.

The *fourth step* is to evaluate the experimental and other data to reach conclusions based on the exercise of scientific judgments.[4] An essential aspect of evalu-

[4] Statistical evaluation of numerical data, with a determination of its "statistical significance", is central to good science. These well-defined, simple equations that all scientists learn while in training determine whether differences between the experimental and control groups are "statistically significant" and are unlikely to have occurred by chance; this is most often expressed as the "p value" or "level of confidence."

ating new data is to determine whether it fits logically with the results of other research. If it does, then a comprehensive picture may emerge. If it does not, then the reasons for "not fitting" must be explained through consultation with peers, to search for overlooked variables.[5]

C. Types of data that can be generated, and time periods involved

Depending on the type of data needed to narrow information gaps, different time periods are necessary to conduct the research. If concerted efforts are made, much acute toxicity data can be obtained within a two- to four-month period using rodents and other laboratory mammals. Research concerning long-term ill effects requires 12-24 months and is generally carried out in rodent models that have a natural life-span of 2-3 years.

A wide variety of sophisticated *acute toxicity* data can be generated in 2-4 months, including the following:

1. The amount and rate of absorption via skin, aerosol, and oral intake.

2. The distribution of absorbed material to different organs and mode of excretion or destruction.[6]

[5] Review of the data by peers for adequacy of experiments is crucial for this step. Part of the interaction with peers involves repetition of the experiments by independent groups of scientists to test for reproducibility of results, provided the same protocol is used.

[6] Specifically labelled toxic chemicals, using radioisotopes of carbon (^{14}C), or hydrogen (^{3}H), permit a unambiguous tracing of a chemical into all parts of the body and body fluids; retention and excretion can thereby be determined. Other toxic substances may be detected through their characteristic structure, or their conversion to a distributive metabolite; the use of modern analytic methods such as gas chromatography/mass spectrometry (GC/MS) with a computerized library of mass spectrometry structures, or high pressure liquid chromatography (HPLC), permit the detection of very minute quantities of chemical substances, even in large volume organs such as the liver and brain.

3. The acute effects on the structure and function of vital organs (brain, lungs, heart, liver, kidneys, etc.).[7]

4. Determination of the above (1-3) on different species, at different ages, and under specific physiology conditions such as pregnancy and embryonic states.[8]

II. OSHA Should Make Appropriate Use Of Science In Setting Health Standards

The benzene case seems to be an example where OSHA could have made use of the American scientific

[7] Examination of the structure of tissues from autopsied animals can be accomplished within 24 hours. The function of vital organs can be assessed in varied ways. Brain function can be examined by behavioral studies, in terms of learning and memory, or electrodes may be placed under anesthetic into different parts of the brain to study reflexes and individual nerve cells; this may take between 2-8 hours per rodent. Similarly, tests of cardiac, pulmonary, liver and kidney function may be done on intact animals by materials injected into the blood, and analyzing blood chemicals.

[8] Effects on humans can often be determined through retrospective studies of exposed individuals, provided adequate medical records are available, together with appropriate controls that have been matched for age, sex, race, socioeconomic status, habits such as alcohol and tobacco, and nutritional status. Retrospective epidemiology studies like this can be accomplished within four months.

community in making regulatory decisions to protect workers. We do not know when OSHA first decided to regulate occupational exposure to benzene. The explanation for OSHA's regulatory decision first appeared when OSHA issued an Emergency Temporary Standard ("ETS") in 1977.

OSHA presumably knew at the time it issued the ETS that an important issue was raised regarding dermal contact. The two obvious potential toxic effects from dermal contact are dermatitis and absorption of benzene through the skin.

Perhaps the best approach for protecting workers would have been the scientific one, as contemplated by the statute. OSHA could have sought to determine what information was needed to support a reasonable regulation based on sound scientific data. In doing so, OSHA could have followed the four-step scientific inquiry outlined above.

Had OSHA done so, it would have identified the data needed to reach a sound scientific conclusion on the exposure to workers by absorption from dermal contact with mixtures containing benzene. By a simple inquiry to the scientific community, OSHA could then have determined the length of time it would take to generate that data.

The question of whether the skin absorbs benzene involves a relatively simple and standard procedure. A number of biomedical research facilities would be able to generate data on skin absorption in a two- to four-month period.

It is *not* suggested that all the data needed for OSHA can be generated in two to four months, but it happens

that skin absorption data fall within the two- to four-month category. We further recognize that there may be other situations where the hazard is such that OSHA could not reasonably await the outcome of experiments which require two to three years to complete. We believe, however, that if OSHA establishes priorities for substances it proposes to regulate, the need for data can be identified sufficiently *in advance* of the issuance of regulations, and in many cases the necessary data can be generated before the completion of the regulatory procedure.

From a scientific view, a sound decision cannot be made without valid data from research and experiments. It seems incongruous, from a scientific point of view, that OSHA should purport to issue a regulation to control absorption of benzene by dermal contact when OSHA believed that the data on skin absorption were "extremely limited" and "not definitive". To issue a regulation on this basis is not consistent with the concept of a statute that directs reliance on "research and experiments", particularly when the scientific data can be secured easily, reliably, and in a short time.

The Court of Appeals concluded that OSHA had not followed the Act by relying on "old and inconclusive" data when scientific data on skin absorption were "readily available". Our previous description of data which can be developed in a two- to four-month period would lend support to that conclusion and provides a basis on which this Court can determine whether it was reasonable for OSHA to act on the basis of the data before the Agency.

We do not offer a generic definition of data that are "readily available". From a scientific point of view,

whether data are "readily available" must be judged in the light of the need for data. Where immediate, emergency action is imperative, time becomes critical in deciding what information is readily available. It appears to us that the procedures OSHA followed in the benzene case did not make optimum use of the available time to develop a sound regulation. OSHA presumably knew months in advance of the issuance of the final regulation that the data on skin absorption were not adequate, and that a real need existed. There would have been sufficient time to obtain the needed data, had OSHA pursued the direction from Congress to issue standards based on experiments and research.

III. The Biomedical Research Establishment Has The Capability To Supply Scientific Data Required To Implement The OSHA Statute

The biomedical establishment in the United States is large and well staffed. The university biomedical research establishment provides a good example of these capabilities.

There are approximately 200 identified university research centers that carry out major biomedical research, largely with funds from the National Institutes of Health, the National Science Foundation, federal contracts and other sources. Within these 200 biomedical research centers there are approximately 15,000 senior level scientists (full-time, and tenured as associate and full professors), plus 25,000 junior level scientists (post-doctoral fellows and assistant professors); the technical research support staff is estimated at 20-40,000 and includes laboratory technicians, and animal care personnel. Many of these institutions have large numbers of additional personnel, but the above cited numbers reflect estimates of those engaged in full-

time research; it does not include those who are predominantly providing clinical or educational services.

The biomedical capabilities of the United States have been developed as a result in large measure of the extensive experimental programs of the National Institutes of Health, the National Science Foundation, and other governmental programs. Up to the present, the university biomedical research establishment has been geared to U.S. research programs originated by the academic scientists. The capabilities were designed to carry out those programs. The university biomedical research establishment has not been utilized to any great extent by OSHA because OSHA has not made any systematic attempt to take advantage of the research and experimental capability of the academic biomedical research community.

Traditionally, OSHA has tended to be passive so far as research and experimentation are concerned. If scientific data were presented at a hearing, OSHA considered them. OSHA has not been in the forefront of identifying and seeking out the data which it needs for scientifically based regulations.

OSHA could take *affirmative action* in securing the new data needed by streamlining short-term research contracts through a list of "pre-qualified contractors." For example, there are several potential administrative mechanisms to cut "red tape" and allow greater joint ventures between OSHA and the university scientists. It is *not* the purpose of this brief to advocate any specific administrative means for streamlined contracting, but such means are readily formulated. We would suggest that if streamlined contracting were to be created, that on any one major scientific question, contracts be awarded simultaneously to three independent

groups. If all three followed the same protocol of procedures and analyses, then reproducible data would be more rapidly forthcoming.

In considering the capabilities of the U.S. academic medical research community to be of assistance to OSHA, it is fair to question why current data, most of which has been generated by the university scientists, are not sufficient for OSHA's needs.

The principal reason is that the scientists of the university biomedical research establishment are not responsible for, nor do they have information on, regulatory priorities. Since OSHA has rarely indicated an interest in using the biomedical establishment to provide the research and experimental data OSHA needs, the data have not been developed. Rather, the capabilities for research and experimentation are designed to respond to U.S. research programs initiated by the academic scientists. Data needed by OSHA are generated only incidentally as part of those research programs.

It is not reasonable to expect experimental scientists to predict the needs of OSHA for new scientific data. If, however, the Court affirms the statutory objective that OSHA rely on research and experimental data, then we believe OSHA can no longer be the passive receptor of information which in many cases could be insufficient for OSHA's needs. If, as we understand the statute, the intention is that OSHA rely on research and experimental data, then the scientific approach to the evaluation of data, identification of gaps, and the development of data to fill the gaps dictates that OSHA take an *active,* rather than a passive role toward the development of new and vitally needed information.

If OSHA assumes the appropriate attitude toward science, its needs can be served by the biomedical establishment.

A major objection that may be made by OSHA's relying on new scientific data obtained through streamlined contracting mechanisms is that data are frequently the subject of scientific controversy. Scientific controversy is more often seen with respect to long-term testing and chronic effects, and in general, there is relatively less controversy with respect to short-term (2 to 4 months) tests dealing with acute toxic effects. The simultaneous conduct of short-term research by three different groups would lend further assurance of less controversy. The fact that some controversy may exist should not lead to the nihilistic conclusion that OSHA cannot rely on new research and experimental data.

The basic proposal of this brief, that science be utilized to help create a better workplace through greater cooperation with a government regulatory agency, is not new. Rather, it has been used by others, including the Environmental Protection Agency, through the use of contracts and scientific advisory committees. An appreciation of the increasing importance of science, as the basis for public policy decisions by regulatory agencies has resulted in the following, as but a few examples: an inspection program of laboratories by the Food and Drug Administration; the development of governmental standards of good laboratory practice; and the coordination by the regulatory agencies of information on research programs. It appears fully appropriate for OSHA to exercise its statutory duty to seek out new data, for regulatory purposes, through

"... research, demonstrations, [and] experiments...."
The nation's academic research community can help.

CONCLUSION

The attitude we have attempted to convey is that if, as is increasingly true, science becomes an important basis for public policy decisions, scientific regulatory agencies have an obligation to assure that sound science is used. We have suggested ways in which a program to accomplish this purpose might be approached. We urge that if OSHA takes the initiative which we believe it should, then the scientific community can respond to OSHA's needs.

What we are proposing is the opposite of delay or awaiting "one more study". If OSHA acknowledges its responsibility to identify the data it needs and the scientific community is informed of OSHA's priorities, the data can be generated in most cases in a reasonable time frame.

OSHA can see to it that the data are generated with scientific rigor and can validate data by replication and peer review. Scientifically sound regulation based on "research, demonstrations, [and] experiments" which constitute the "best available evidence" will be the result, rather than questionable regulations based on incomplete data.

Respectfully submitted,

JAMES R. RICHARDS
1101 17th Street, N.W.
Washington, D.C. 20036
Counsel

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